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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,261	11/01/2006	Gordon D. Ross	3593.1000-003	9677

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EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
02/14/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,261	ROSS ET AL.	
	Examiner	Art Unit	
	DEBORAH A. DAVIS	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed November 29, 2010 has been received and entered. Currently, claims 1-8 are pending in the application. Claim 8 is withdrawn and claims 1-7 are under consideration for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jamas et al (US 5,488,040) in view of Patchen (US 6,117,850) for reasons of record and restated below:

The claims are drawn to a method of enhancing glucan-mediated committed stem cell proliferation and expansion after injury via the complement system pathway, comprising administering to an individual a therapeutically effective orally bioavailable amount of whole glucan particles.

The reference of Jamas et al. beneficially teaches that soluble β-glucans can be administered orally (bioavailable) to treat animals or humans (individuals) who are at risk of infection due to surgery, injury, illness radiation or chemotherapy and also includes wound healing healing (i.e. tissue repair). In the background of the invention, Jamas discloses that various preparations of both particulate and soluble β-glucans

have been tested in animal models to show the hemopoietic effects of increased peripheral blood leukocyte counts and bone marrow that reflect the increased numbers of progenitor cells (proliferation), and splenic pluripotent stem cells (column 1, lines 62-67, column 2, lines 1-13, column 4, lines 1-16, e.g). Data from invitro or animal testing is sufficient to support that the process or product has this therapeutic utility in humans (see M.P.E.P. 2107.03). The instant specification (see page 3) states that committed stem cells can include progenitor cells. Therefore the splenic pluripotent stem cells and progenitor cells of Jamas read on committed stem cells, as claimed. Although the reference of Jamas does not teach the administration of whole glucan particles (WGP) in its method, the soluble β-glucans are made from WGP and according to the teachings in the background of the reference, both the soluble and WGP will increase (proliferate) the number of stem cells. With respect to the limitation of claims 1-7 that recites that glucan activates and enhances stem cell proliferation via complement system pathway would be inherent upon the administration of β-glucan taught by Jamas. The instant claims describes a mechanism that applicant has elucidated but such a mechanism would be inherent because the method steps of administering β-glucan are the same as instantly clamed and therefore would travel the same complement pathway.

The reference of Jamas does not teach wherein the committed stem cells are selected from the group consisting of stem cells from liver, heart, muscle, kidney and neural tissue.

However, the reference of Patchen et al. beneficially teaches a method of inducing mobilization of peripheral blood precursor and progenitor cells from hematopoietic organs of the body such as bone marrow, liver or spleen by administering aqueous soluble β-glucan to a patient. The β-glucan can be administered orally, paternally, and intravenously (column 4, lines 61-67, e.g.). Once these cells are mobilized and expanded (proliferation) they are reinfused into the individuals that have gone through chemotherapy or radiation therapy (see column 5, lines 20-67, column 6, lines 1-17, e.g.).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the references of Jamas in view of Patchen based on their beneficial teachings of administering β-glucan to an individual for progenitor cell proliferation after chemotherapy. It would have been further obvious to select cells from organs such as the liver, or spleen because they can become damaged through chemotherapy and therefore need to be replenished.

Response to Arguments

Applicant's arguments filed November 11, 2010 have been fully considered but they are not persuasive of error.

Applicant argues that the claims are drawn to using whole glucan particles (WGP) and in contrast, the prior art of Jamas teaches using neutral soluble glucan particles. Applicant argues that Jamas is using different glucan particles and to treat a different population of stem cells. Applicant argues that Jamas teaches a method of

using neutral soluble glucan particles to enhance hematopoietic stem cells which are not committed stem cells. Applicant argues that the specification makes a distinction between committed stem cells and hematopoietic stem cells. Applicant concludes that the examiner has not made a prime facie case and the prior art of Jamas is not obvious over the instant claims. These arguments have been carefully considered but not found to be persuasive of error.

In response, applicant does not include an express definition of committed stem cells but only a broad definition. Applicant's specification describes committed stem cells as: "can be progenitor cells for various organs or tissues such as cardiac stem cells, hepatic stem cells, kidney stem cells, neuronal stem cells, muscle stem cells as well as other stem cells". Although the instant specification does not identify hematopoietic stem cells by the title of "hematopoietic committed stem cells", the specification also does not identify cardiac stem cells by the title of committed cardiac stem cells. Yet, the specification provides in Examples 1 and 2, cardiac stem cells as being enhanced by glucan after injury. The cardiac stem cells are not identified by the title "cardiac committed stem cells", but they are understood to be committed stem cells based on applicant's broad definition of committed stem cells and applicant's only provided example. The stem cells that applicant mentions throughout the specification are not called committed stem cells. Thus, based on applicant's broad definition of committed stem cells, hematopoietic stem cells read on committed stem cells. With respect to applicant's argument of Jamas using neutral glucan particles and not whole glucan particles is not persuasive because although not a whole particle is being used,

the active portion from the whole particle is being used and for the same purpose of enhancing stem cells, as claimed. Further, the cited reference of Jamas discloses that whole glucan particles are known in the art for treating progenitor stem cells.

Applicant argues that the reference of Patchen does not add to the deficiencies of the reference of Jamas. Applicant argues that Patchen is not cited in the first paragraph of the rejection and it is unclear whether it is part of the rejection. Applicant argues that the reference of Patchen only teaches the same subject matter as do Jamas. These arguments have been fully considered but not found to be persuasive of error.

The examiner inadvertently left out typing Patchen in the statement of rejection. However, Patchen was included throughout the rejection, in the motivation statement and cited on the 892. The reference of Patchen was clearly used in the rejection of record. However, the examiner has typed Patchen in the rejection line to make the rejection of record more clear.

The reference of Patchen was relied upon for its teaching of the dependent claim limitations that require glucan particles to enhance the proliferation of stem cells from the spleen, and liver. Both references of Jamas and Patchen are properly combined and are deemed obvious over the claimed subject matter. Although the instant claims does not expressly teach the all limitations of the instant claims, the difference between the cited references and what is known in the art at the time the invention was made with respect to whole glucan particles and glucan particles are obvious because they are used for the same purpose of enhancing the proliferation of stem cells. Further,

applicant has broadly defined committed stem cells to read on the stem cells taught by Jamas and Patchen. Thus, for reasons of record and above, the art rejection is maintained and made final.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner, AU 1655
February 2011

/Christopher R. Tate/
Primary Examiner, Art Unit 1655